

REMARKS

Applicants respectfully request reconsideration of the rejections set forth in the Final Office Action mailed on October 20, 2003. Claim 40 has been amended. Claim 45 has been cancelled herein. Claims 40-43 and 51 are pending. All claims have been rejected.

This amendment is to expedite prosecution and should not be construed as acquiescence in any ground of rejection. Applicants reserve the right to prosecute the originally filed claims in the future.

The amendment recites "code for producing a fingerprint . . . from the morphological values" and "code for producing a statistical profile . . . by *statistically comparing said fingerprint against fingerprints associated with known behaviors in a database.*" As the Examiner indicated in the Final Office Action, the specification enables a fingerprint implementation of the invention. Specific support for the claim amendments is found at pages 14, 15, and 24, for example, where it is pointed that fingerprints comprise multiple descriptors such as the morphological values presented in the claims and fingerprints may be employed in statistical comparisons with fingerprints in databases. The fingerprints in the database may characterize cellular manipulations having known behaviors (e.g., mechanisms of action, toxicities, patient responses, gene responses, and the like). See page 24, first full paragraph.

Rejections under 35 U.S.C. §112, 1st Paragraph

Enablement

The claims have been rejected under 35 U.S.C. §112, 1st paragraph for alleged lack of enablement. Specifically, the Examiner maintains that the specification lacks guidance, direction and examples for deriving the morphological values and is not commensurate in scope with the claims. Applicants respectfully traverse this rejection.

Applicants acknowledge with appreciation the Examiner's further clarification of this rejection. Specifically, the Examiner has stated that while the specification enables a *fingerprint* implementation of the invention, it does not enable other implementations and so the scope of enablement in the specification is not commensurate in scope with the scope of the claims – which are not limited to fingerprint implementations.

Applicants respectfully dispute the contention that the scope of enablement in the specification is not commensurate with the scope of the claims. A skilled programmer or other

technical person charged with implementing the claimed invention algorithmically and through development of necessary computational constructs would have little difficulty, it is submitted, in performing this task using only the teachings of the specification and routine skill in the art. A brief description of each element of independent claim 40 may help.

The claim first recites "code for capturing a morphological value from each of said plurality of manipulated cells for each of said plurality of different cell lines." This morphological value may be "a cell count, an area, a perimeter, a length, a breadth, a fiber length, a fiber breadth, a shape factor, an elliptical form factor, an inner radius, an outer radius, a mean radius, an equivalent radius, an equivalent sphere volume, an equivalent prolate volume, an equivalent oblate volume, an equivalent sphere surface area, an average gray value, a total gray value, or an optical density." It is respectfully submitted that each of these is a well-known mathematical characteristic that can be captured from an image, for example, using routine skill. As indicated in the specification, an image may be digitized and morphological values from manipulated cells can be captured. See e.g., Figures 2C and 2D and the associated discussion in the specification.

This first claim element requires nothing more than capturing a value (e.g., a numerical/scalar value) by whatever means is appropriate given the type of cells under consideration and the system employed to observe the cells. It is not seen that any special techniques are required to capture any of the various values identified in the claim. For example, routine thresholding, edge detection, etc. can be employed for this purpose as mentioned at page 18, first full paragraph et seq. These and other well-known related techniques allow one to simply and effectively identify cells, and characterize geometric (morphological) features of the cells. For context, an example of a cell observation and image capture methodology is described at page 17 with reference to Figure 2C.

Because claim 40 has been amended to recite a fingerprint implementation, the next two claim elements (reciting code for "assigning a degree of presence for each of said morphological values" and "storing said degrees of presence") are unnecessary. The fingerprint is produced from morphological values, regardless of whether those fingerprints are provided directly or indirectly, as in the case of a "degree of presence." Because a fingerprint need not (but may) include a "degree of presence," the second and third claim elements have been deleted.

Next the claim recites "code for producing a fingerprint characterizing the manipulated cells, wherein the fingerprint comprises morphological values for the plurality of manipulated cells for each of the plurality of different cell lines." As indicated in the specification, a fingerprint comprises descriptors (e.g., morphological values some of which are identified in the

table on pages 13-14) which in combination characterize the cells and a cell-manipulation interaction. In one specific implementation, a fingerprint is a "vector of two more scalar values extracted from a plurality of cell lines and markers grown in the same condition together." See page 24, first full paragraph. Obviously, producing a fingerprint (e.g., a vector) comprising morphological values (alone or in combination with other types of information) requires only routine mathematical or algorithmic skill using the teachings of the present specification. Essentially, all that is required is a computational mechanism for grouping or associating the constituent morphological values (or derivations thereof) with one another.

Next the claim recites "code for producing a statistical profile of said manipulated cells by statistically comparing said fingerprint against fingerprints associated with known behaviors in a database." As the examiner acknowledges the specification enables a fingerprint implementation of the invention. Fingerprints, as multivariate representations of the effect of a manipulation, can provide meaningful classification or mapping when statistically compared against other fingerprints that have been previously mapped or classified. The cell response or behavior induced by the manipulation in question can be a mechanism of action (of a drug for example), a toxicity, a patient response, etc. as pointed out on pages 15 and 24. Implementation of the code for producing a statistical profile in this manner would not require undue experimentation. As pointed out in the specification, a phylogenetic tree, for example, can be used to identify the statistical significance of similarity between fingerprints of drugs (one example of a manipulation) in a database. Other statistical techniques such as clustering and various heuristic techniques can be used for the same end. Database query technology for making such statistical classifications is mature, well understood and easy to implement. It is respectfully submitted that no more than routine skill is required produce the code for producing a statistical profile as required by the claim.

Next the claim recites "code for mapping said plurality of manipulated cells based upon said statistical profile." This simply provides the means to conclude the analysis. Having a statistical profile obtained from the fingerprint comparison, the computational system is simply asked (by virtue of this code) to "map" the manipulated cells. In a typical example, the mapping is between the cells (and associated type of manipulation) and an underlying behavior (e.g., mechanism of action) of the manipulation. Writing code to perform such mapping will typically be trivial. For example, the database will have known behaviors associated with fingerprints. The statistical profile may specify a likelihood that a given behavior is associated with the manipulation under investigation. The behavior and in some instances the likelihood as well is provided in the mapping.

Finally, the claim recites "a computer readable storage medium for holding the codes." Nothing needs to be said here. The Examiner has not indicated there is any issue with this claim element.

Applicants respectfully submit that the claims are enabled according to the standards set forth in the M.P.E.P. and caselaw. As mentioned, Applicants believe that a programmer, computer engineer, mathematician, or other professional with the relevant skill in the art could readily create code to capture morphological values, produce a fingerprint, produce a statistical profile, and map the effect of the manipulation based upon the statistical profile. Applicants respectfully submit that the claims are enabled under the relevant standards enumerated in previous responses and request withdrawal of this rejection.

Applicants believe that the claims are allowable and respectfully request a Notice of Allowance for this application from the Examiner. Should the Examiner believe that a telephone conference would expedite the prosecution of this application, the undersigned can be reached at the telephone number set out below.

Respectfully submitted,
BEYER WEAVER & THOMAS, LLP



Jeffrey K. Weaver
Reg. No. 31,314

P.O. Box 778
Berkeley, CA 94704
510-843-6200